CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 40-323

BIOEQUIVALENCE REVIEW(S)

OFFICE OF GENERIC DRUGS

DIVISION OF BIOEQUIVALENCE

ANDA # 40-323 SPONSOR: UDL Laboratories Inc.
DRUG AND DOSAGE FORM: Prednisolone Syrup, USP
Strength(s): 15 mg/5ml
Type of Study: SD SDF MULT OTHER
X

STUDY SITE: N/A
STUDY SUMMARY: N/A
FORMULATION: Acceptable
Waiver is granted.

PRIMARY REVIEWER: Mamata S. Gokhale, Ph.D. BRANCH: III
INITIAL /S/ DATE 9/30/98

TEAM LEADER: Barbara M. Davit, Ph.D. BRANCH: III
INITIAL /S/ Date 9/30/98

DIRECTOR: Dale P. Conner, D.Pharm.
DIVISION OF BIOEQUIVALENCE
INITIAL /S/ DATE 10/1/98

DIRECTOR
OFFICE OF GENERIC DRUGS
INITIAL _____ DATE _____

A 1.

Prednisolone Syrup, USP
15 mg/5ml
ANDA # 40-323
Reviewer: Mamata S. Gokhale
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UDL Laboratories, Inc.
7265 Ulmerton Road
Largo, Fl 33771
Submission Date: June 30, 1998

Review of a Waiver Request

Background

1) The firm has submitted a request for a waiver of in vivo bioavailability/bioequivalance study requirements based on 21 CFR 320.22(b)(3) for its proposed product Prednisolone Syrup, USP, 15 mg/5ml. The reference listed drug is Prelone® Syrup, 15 mg/5ml (NDA #N89081 001) manufactured by Muro Pharmaceutical Inc.
2) Prednisolone is a glucocorticoid with potent anti-inflammatory effects which are indicated in diseases of various organ systems like endocrine, rheumatic and hematologic disorders; collagen, dermatologic, opthalmic, respiratory, neoplastic and gastrointestinal diseases; as well as in allergic and edematous states. It is also used as replacement therapy in adrenocortical deficiency states.
3) The reference product, Prelone® Syrup, 15 mg/5ml, is to be administered by oral route. The test product, Prednisolone Syrup, USP, 15 mg/5ml, is proposed to be administered by similar route.

Formulation Comparison

Formulation(per ml)	Reference listed product	Test product
Active Component		
Prednisolone, USP	3 mg	3 mg
Inactive Components		
Edetate Disodium, USP		
Propylene Glycol, USP		
Glycerine, USP		
Benzoic Acid, USP		
Saccharin Sodium, USP		
Sucrose,		
Alcohol, USP		
Dye FDC Red #40		
Dye FDC Blue #1		
Flavor Wild Cherry		
Purified Water, USP		

•Within safety limits approved by FDA in the CDER inactive ingredient guide, ⁺Anhydrous in test product, not specified in reference listed product, ⁺⁺Approved up to 0.4 mg/ml, in the CDER inactive ingredient guide, ♦Wild Cherry Flavor at s approved. See ~~NDA~~ 1980 and ANDA 1994.

ANDA

Comments

1) The proposed product is a syrup intended for administration solely by the oral route.
2) The active ingredient, route of administration, dosage form and strength of the test product are same as those of the reference listed product.
3) The proposed product contains no inactive ingredient that may significantly affect absorption of active drug ingredient.

Recommendations

The Division of Bioequivalence agrees that the information submitted by UDL Laboratories, Inc. demonstrates that Prednisolone Syrup, USP, 15 mg/5ml, falls under 21 CFR 320.22(b)(3) of the Bioavailability/Bioequivalence regulations. The waiver of an *in vivo* bioequivalence study requirement for, Prednisolone Syrup, USP, 15 mg/5ml, is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test product to be bioequivalent to Prelone® Syrup, 15 mg/5ml manufactured by Muro Pharmaceutical Inc.

Mamata S. Gokhale, Ph.D. /S/ 130/98
Review Branch III
Division of Bioequivalence

RD INITIALED BDAVIT bwd 9/29/98
FT INITIALED BDAVIT /S/ Date 9/30/98

Concur: /S/ Date 10/1/98
Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA # 40-323 APPLICANT:.UDL Laboratories Inc.

DRUG PRODUCT: Prednisolone Syrup,USP
15 mg/5ml

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

/S/

Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research